

**Notice of Allowability**

Application No.

09/646,924

Applicant(s)

RASPE ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/10/05.
2. ☒ The allowed claim(s) is/are 1,10,12,22,25,26,31 and 32.
3. ☒ The drawings filed on 25 September 2000 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
6/17/05

**DETAILED ACTION**

1. Applicants' response to the office action and amendment filed on June 10, 2005 have been considered and entered.

2. The rejection made in the previous office action under 35 USC 112, first paragraph written description is withdrawn herein in view of the amendment.

2. The following is an examiner's statement of reasons for allowance:

Claims 1, 10, 12, 22, , 25-26, 31-32 are allowed.

The present invention is drawn to a method of screening a substance for usefulness in the treatment of a lipid metabolism dysfunction comprising contacting said substance with a response element of human ROR $\alpha$  of the human apo C-III promoter and measuring the expression of apo C-III gene expression. The closest prior art (Karanthanas et al., US 5, 721,016) teach a method for screening a compound in response to a transcription factor and expression of apo I gene and did not teach screening of a substance related to lipid metabolism that modulates apo C-III gene expression. Fraser et al. (J Biol. Chem., Vol. 272(21), 13892-13898, 1997) teaches a method for expression of apo C-III gene in the presence of a hepatocyte nuclear factor. With regard to the obviousness rejection (Karanthanas et al. in view of Fraser et al), Applicants' arguments are found persuasive since there is no motivation to combine the method of Karanthanas et al. with the method of Fraser et al. Thus Karanthanas et al. in view of Fraser et al did not teach or suggest a method for screening a substance that modulates the apo C-III gene expression involved in lipid metabolism. Thus the instant invention was not taught or obvious over the closest prior art. Further the instant amended claims obviated the rejection under 35 USC 112, first paragraph, written description.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

<sup>SPC</sup>  
Suryaprabha Chunduru.  
June 17, 2005.

JEFFREY FREDMAN  
PRIMARY EXAMINER

6/13/05